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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,898	10/03/2001	Zhiyuan Gong	1781-0163P	5940

2292 7590 11/17/2004

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/913,898	GONG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph T. Voitach	1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-11, 13, 16 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-11, 13, 16 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

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### **DETAILED ACTION**

The previous action mailed October 5, 2004 has been vacated. A new action on the merits is presented below.

This application is a 371 national stage filing of PCT/SG99/00079, filed July 16, 1999 which claims benefit to foreign application 9900811-2, filed February 18, 1999 in Singapore.

Applicants' amendment filed September 2, 2003, has been received and entered. Claims 1-6, 12, 14, 15, 17 and 18 have been canceled. Claims 19-21 have been added. Claims 7-11, 13, 16, 19-20 are pending.

It is noted that the amendment filed on May 12, 2003, paper number 12, canceling all claims drawn to the inventions set forth in the restriction requirement and presenting only claims drawn to a new invention is non-responsive (MPEP § 821.03) because it was acknowledged by Applicants, the remaining claims are not readable on the elected invention.. As such the amendment was not entered.

### ***Election/Restriction***

Applicant's election without traverse of group VIII in the reply filed on August 27, 2003 is acknowledged. Newly added claims 19-21 are drawn to the elected invention, and will be examined to the extent they encompass the elected invention. Claims 7-13, 16, 19-21 as they are drawn a transgenic fish comprising a zebrafish fast muscle isoform of myosin light chain 2 gene promoter are currently under examination.

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Applicants have indicated in their response that it is understood that claims will first be examined as they read on the elected invention and then, if allowable will be examined generically. However, it was noted in the restriction requirement, that under Rule 13.1-13.2 the allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. In the instant case, Applicants claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. Specifically, claim 7 encompasses the use of four specific different promoters to generate four different fish which are structurally and functionally different. Further, upon review of the claims recited in the group, it is found that claim 10 is more generic than the restricted groups, and would be considered a generic linking type claim common to each groups V-VIII, and will be examined to the extent that it encompasses the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 7-13, 16, 19-21 as they are drawn a transgenic fish comprising a zebrafish fast muscle isoform of myosin light chain 2 gene promoter are currently under examination.

***Claim Objections***

Claim 7 is objected to because of the following informalities: Claim 7 depends on claims 1-4 which have been cancelled.

Claim 10 is objected to because of the following informalities: Claim 10 is generic and broadly encompasses non-elected inventions. The claim should be amended to reflect the elected invention of a transgenic fish comprising a zebrafish fast muscle isoform of myosin light chain 2 gene promoter.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case, the specification does not support the breadth of the newly added claims. Literal support for 'ornamental fish' can be found in the specification on page 4, however the only fish contemplated are those containing "[T]hese chimeric gene constructs useful to generate green fluorescent transgenic fish." Presumably discussed above in the specification. The

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specification does not support using any possibly conceived construct nor does it support broadly expressing other fluorescent proteins other than GFP in ornamental fish. Further, the specific embodiments of breeding and expression levels for fluorescence when exposed to sunlight are not recited nor taught.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 19-21 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" .

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are 7-9, 11, 13, 16 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is incomplete and unclear because it recites the use of a promoter from other claims, however these claims have been cancelled. The claim should be amended to clearly reflect the embodiments previously set forth in the cancelled claims.

Claim 8 is unclear and confusing because transgenic animals contain a copy of the transgene in every cell, somatic and germ cell, and are capable of producing viable offspring if the transgene expression is not lethal. The claim is unclear because it is not clear how claim 8 further limits claim 7 because it simply recites inherent properties of a transgenic fish.

Claim 9 is incomplete because if one were to mate the transgenic fish with a non-transgenic fish a possible progeny of the F2 generation is a fish without the transgene, which would not emit green fluorescence. Clearly indicating that the progeny contains the transgene would obviate the basis of this rejection.

Claims 11 and 21 are vague and indefinite because the level of expression will be relative to the level of sunlight. The metes and bounds of the claims can not be specifically defined because they are relative to two variable factors and to what one would consider "sufficient" and to the means of detecting the fluorescence.

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Claim 16 is indefinite in the recitation of “hybridizes under stringent conditions” because stringent is not specifically defined in the art and is subject to change from one artisan to the next. The metes and bounds are relative to the artisans interpretation and not specifically defined in the art.

Claims 19-21 are indefinite because the metes and bounds of what would be considered an “ornamental fish” is not set forth in the claims nor defined in the specification. It is unclear what specific fish are included or excluded from this term.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11, 13, 16 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Moss *et al.* (IDS reference).

Moss *et al.* teach a zebrafish which comprises a myosin light chain enhancer operatively linked to a sequence encoding GFP for the muscle specific expression. Characterization of the resulting fish indicated fluorescence from expression of the transgene was seen uniquely in the muscle and not other non-muscle cells in the fish.

Claims 7-11, 13, 16 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Amsterdam *et al.* (IDS reference).



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Amsterdam *et al.* teach a zebrafish which comprises a strong promoter operatively linked to a sequence encoding GFP for ubiquitous expression. Characterization of the resulting fish indicated fluorescence from expression of the transgene was seen throughout the embryo and resulting transgenic fish.

***Conclusion***

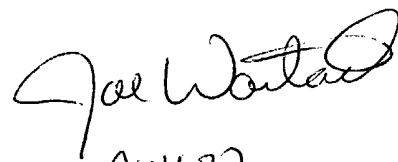
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

  
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